Performance Variability

Identified by Bench Testing of Selected Portable Oxygen Concentrators

Robert McCoy BS RRT FAARC
Managing Director - Valley Inspired Products Inc.

Ryan Diesem BS
Research Manager - Valley Inspired Products Inc.

White Paper

Clinicians need to prescribe and patients need to apply portable oxygen concentrator (POC) technology correctly for appropriate oxygenation and improved outcomes.

Overview

Portable Oxygen Concentrators (POCs) have been available for over two decades, but in recent years interest and use of these devices has increased significantly. Oxygen dependent patients need portable oxygen options that allow for a more normal lifestyle. This requires a light, long lasting ambulatory oxygen system. Durable medical equipment (DME) providers' reimbursement for home oxygen systems has been decreasing, forcing them to find ways to reduce oxygen delivery costs and services to remain viable. DME providers use a variety of portable oxygen solutions such as liquid oxygen (LOX) systems, compressed oxygen cylinders and POCs to deliver service to patients.

LOX systems and compressed oxygen cylinders are being removed as standard delivery options for most DME providers, due to the high delivery costs and operational challenges. Though compressed oxygen cylinders are still widely used, even with an oxygen conserving device, they do not provide a practical lightweight long-lasting portable system. The limitations and high operational costs associated with LOX and compressed gas cylinders has contributed to the popularity of POCs with DME providers and patients.

Some oxygen patients have been put in a situation where they need to find new possibilities to supplement or improve their LOX or compressed portable oxygen options, often requiring the patient to purchase their own oxygen system. With consumers purchasing POCs and some clinicians having limited understanding of the capabilities, limitations and applications of these devices, comparative testing is necessary to understand POC variability so they can be used effectively.

Most patients feel POCs are a commodity product and often look for the lightest weight unit with the longest operating times (battery life). Additional considerations for these patients are the number settings on the device to match their prescription, purchase price and general esthetics since this is a personal purchase decision.

The patient will need a prescription, yet most clinicians are not familiar with POCs and will most likely ask if the device can be set to their oxygen prescription setting. The purpose of this paper is to identify that the number for selection dose/flow is not equivalent to continuous flow (CF) and individual product variability can impact therapy.

Method and Material

Units tested:

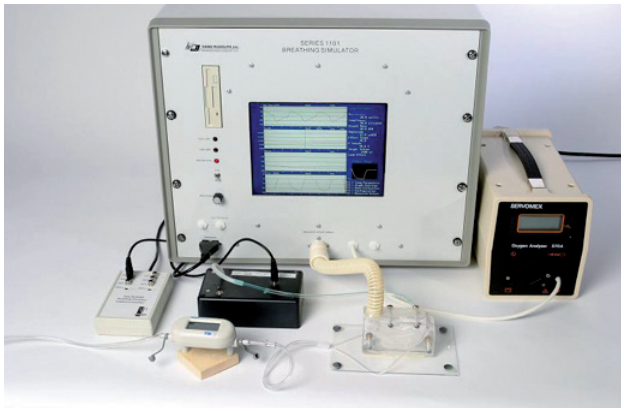
Zen-O Lite
GCE

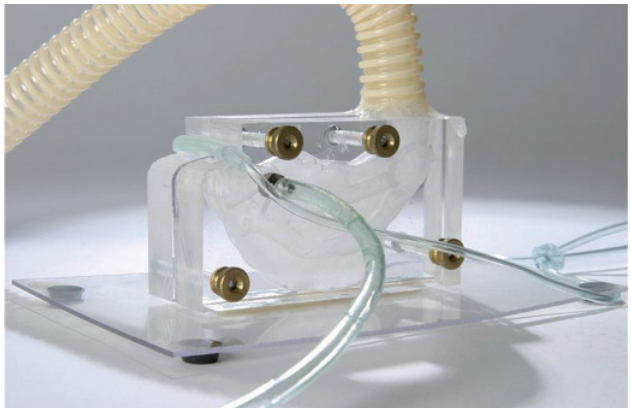
Inogen One G3
Inogen

SimplyGo Mini
Philips Respironics

Platinum Mobile
Invacare

Test Set-Up



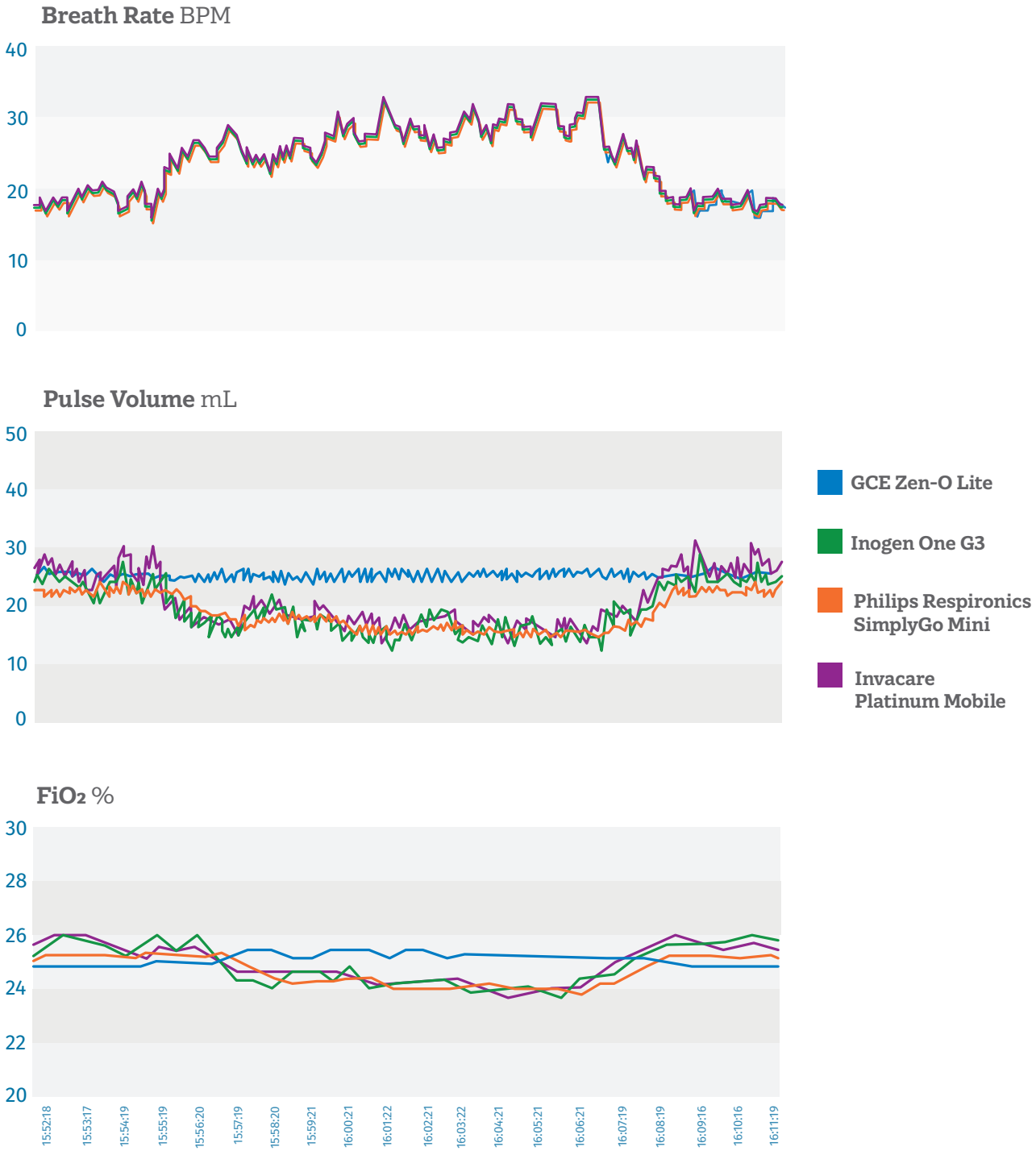


The test combined the pulse delivery and FiO_2% test set-ups, with the Clinical Oxygen Dose Recorder (CODR) placed in-line instead of the TSI® flowmeter. A PC running the CODR software package was used for data collection. The breathing simulator was programmed to run a script based on breath rate data taken from an actual oxygen user, where the user was resting with a 1:2 (I:E ratio), then active with a 1:1 (I:E ratio), then resting again at a 1:2 (I:E ratio). Using the breath rate data and adjusting the amplitude setting to maintain a static 520ml tidal volume (+/- 30ml) throughout the test, the simulator script ran for a total duration of 19 minutes, with FiO_2% data taken every 30 seconds. The CODR and software recorded breath rate and pulse volume delivery on a breath-by-breath basis. Each unit was tested at pulse setting 2 and the maximum pulse setting available on each device. FiO_2%, pulse volumes measured by the CODR, and breath rate data were synchronized and plotted after test completion.

I:E - Inspiration/Expiration ratio (seconds)

Full test set-up is referenced in the Valley Inspired Products' 'Guide to Understanding Oxygen Conserving Devices'

Dynamic Breath Rate Testing



As the patient's breath rate increases the FiO_2% drops for the minute volume devices. The fixed volume device (GCE Zen-O lite) maintains a predictable/ stable FiO_2% while the patient is ambulating.

Findings

Pulse volumes can impact the FiO_2 the patient receives, especially when their breath rate increases from a resting rate to an active rate.

Some of the POCs evaluated in this paper are generally referred to as 'minute volume' devices, as they produce a fixed volume of oxygen per minute, which means that the pulse size for each breath decreases as the breath rate rises, and vice versa. Some of the other POCs evaluated deliver a fixed pulse size irrespective of the patient breath rate – these type of devices are commonly referred to as 'fixed pulse', 'constant bolus' or 'rate responsive' devices.

With a minute volume device, unless the patient increases the pulse setting, a device capable of oxygenating a patient at rest may not be able to oxygenate them at increased activity levels when FiO2 drops significantly (assuming relatively static tidal volume) because the pulse volume is automatically reduced. If the patient can't select a higher setting because they are already at the maximum setting, then that device may not be an appropriate portable option for them.

Straight minute volume delivery POCs (G3, Platinum Mobile) show reduced volume delivery with an increase in breath rate at a given setting, compared to the combination fixed pulse and minute volume POCs (Zen-O lite, SimplyGo Mini). SimplyGo Mini functions as a fixed pulse device up to 20BPM then changes to minute volume delivery above 20BPM. Zen-O Lite functions as a fixed pulse delivery until the maximum available oxygen is exceeded (Setting 2 - 40BPM).

Significant Key Points

Early oxygen conserving devices (OCDs) had fixed pulse delivery as they were incorporated with an oxygen regulator connected to a compressed gas system or LOX system. These gas sources have readily available volume of gas so oxygen access was not limited, which is unlike POCs that instead have limited minute volume production. The fixed dose was variable on the early OCDs based on the manufacturer's specification and no standards for dose volume were established. Marketing claims from manufacturers of the best oxygen conservation ratios compared to continuous flow required a lower pulse volume per setting to accomplish the greatest oxygen saving ratio.

Fixed pulse volume had the benefit of consistent FiO_2 delivery with every breath. This increased the minute volume of oxygen to the patient, allowing them more oxygen when respiratory rate increased, which can be likened to increasing a continuous flow setting. When patients breathe faster, it usually means their oxygen demands have increased so the additional oxygen delivery with fixed pulse would be a benefit.

Continuous flow oxygen, when the setting is left unchanged, is a minute volume delivery approach. With increased respiratory rate, a patient's inspiratory time will decrease meaning less oxygen is inhaled within the shorter inspiratory time. This implies the FiO_2 will decrease with each breath. Years ago, the American Thoracic Society (ATS) oxygen guidelines recommended an increase in CF flow of 1 lpm with exercise. This was due to the understanding of the increased respiratory rate's impact on inspiratory time and oxygenation.

Fig 01: **Pulse Volumes at Active Breath Rates at Pulse Setting 2**

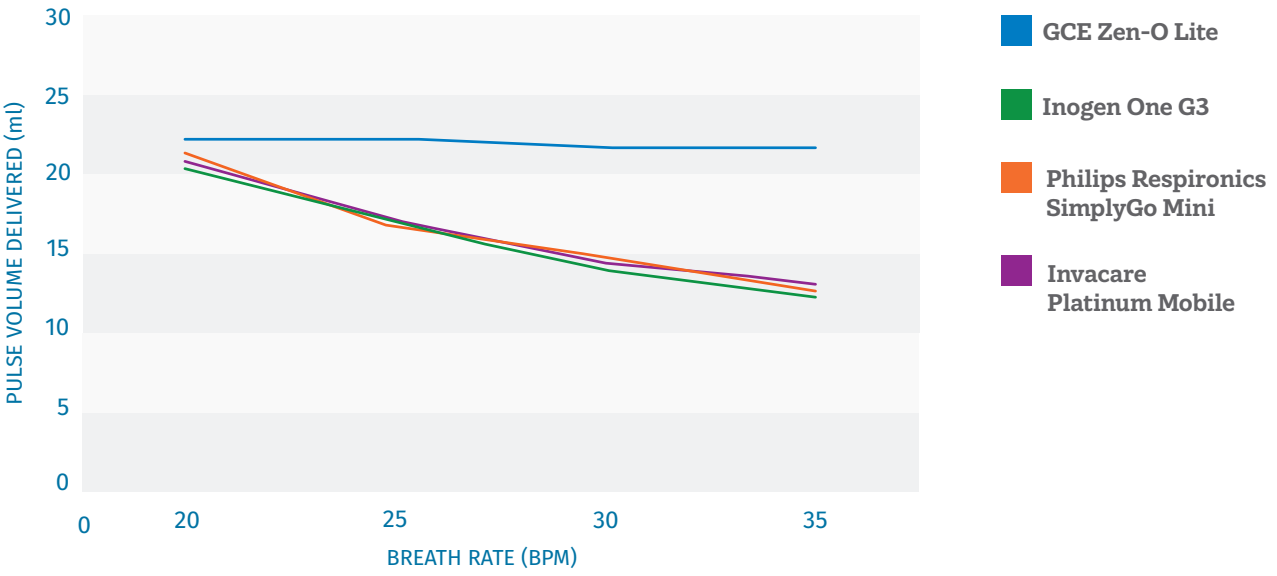
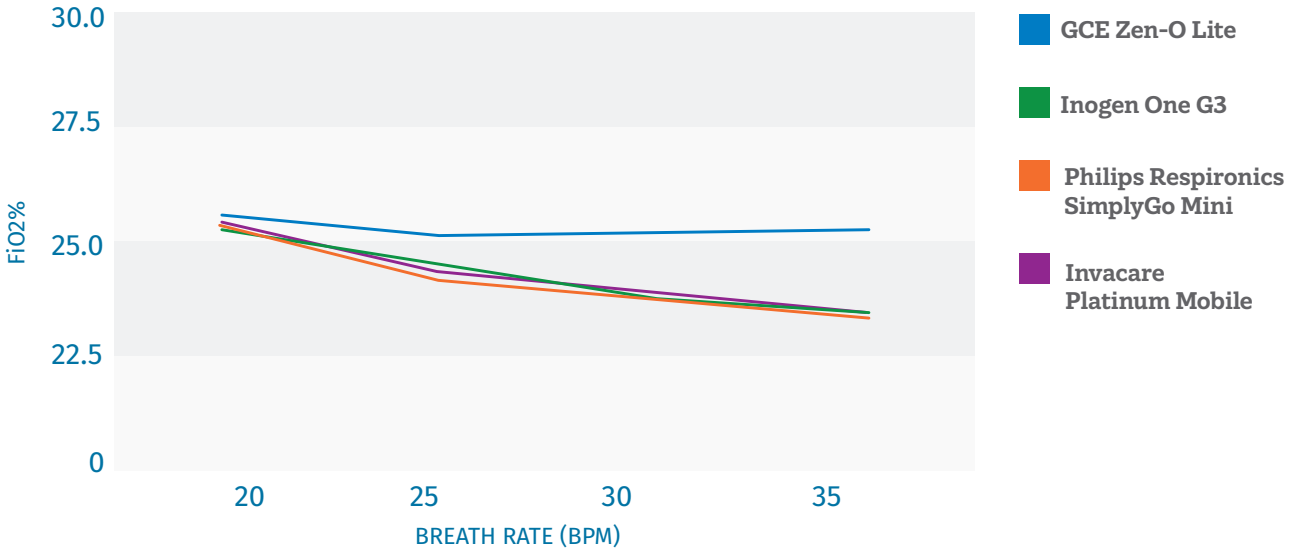


Fig 02: **FiO_2% at Active Breath Rates at Pulse Setting 2**



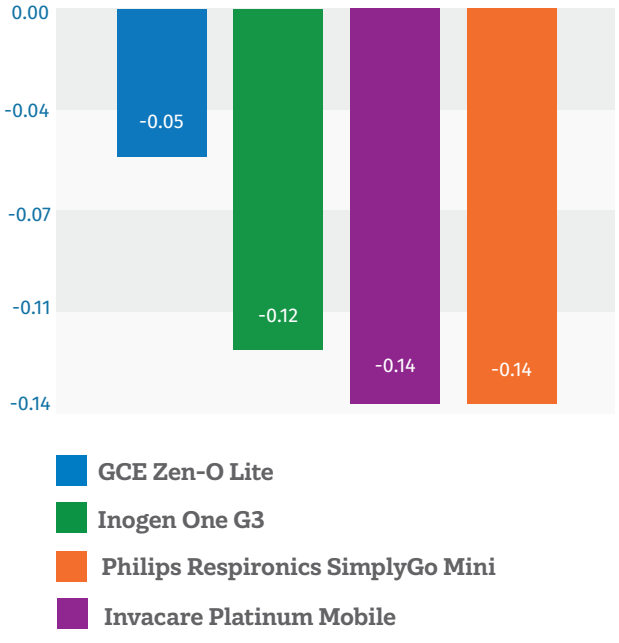
Most POCs operate with a minute volume delivery methodology. This is due to the limited production of oxygen per minute and the claims that this delivery of oxygen is similar to CF. These POCs give larger volumes of oxygen with a slower respiratory rate, yet typically when a patient is breathing slower, their oxygen needs decrease. A POC's ideal application is with activity where the respiratory rate will increase; giving less oxygen when needs increase is not therapeutic, and giving more oxygen when needs are less is confusing.

In Fig 01, the reader can observe the relative stability of the pulse volumes delivered as the breath rises and resultant stability in FiO_2 (Fig 02) from Zen-O Lite versus the other POCs as the breath rate rises. This would imply that POCs like Zen-O Lite delivering a fixed pulse volume may better oxygenate a patient at increased activity levels. A full clinical trial is required to verify this.

Triggering Sensitivity Has Advantages

As well as the variability of the oxygen output from the test devices, there is additional variability found in the sensitivity of the trigger mechanism. A device with a lower sensitivity trigger point may not always deliver the bolus effectively. Conversely, a device with a trigger setting that is too sensitive may auto pulse or not deliver the bolus at the appropriate time. It was noted in the test protocol (Fig 03) that all devices have a standard trigger setting of -0.12 to -0.14 cmH_2O. However the Zen-O Lite (GCE) has a dynamic sensitivity algorithm that varies from -0.12 to -0.05 cmH_2O depending on the breathing pattern of the patient.

Fig 03 **Negative Pressure to Trigger (cmH_2O)**



Discussion

Patients Buying POCs

POC sales are increasing every year as reimbursement is being reduced and portable oxygen options are decreasing. With little help from physicians and some DME providers not interested in these products, many patients are left with the challenge of finding the right POC for their clinical and lifestyle needs. Advertisement for POCs includes very little clinical advice regarding the patients' needs and the devices' capabilities. Advertisements focus on weight, operating times and esthetics with a focus on lifestyles and travel. Patients assume the device they buy will meet their clinical needs based solely on dose settings meeting their prescription. More evidence is being published on the difficulties patients are having in finding solutions to their portable oxygen needs.

Understanding a POC's capabilities, limitations and comparison with other POCs can give a patient some understanding of device operation and variability.

Clinicians not Familiar with Performance Variability

Many clinicians are unfamiliar with oxygen conserving devices or portable oxygen concentrators, so the combination of both virtually eliminates their participation in a POC selection. This research and other similar articles needs to be reviewed and understood by clinicians to have them participate in the selection process. Unfortunately when a patient is on a POC and not oxygenating, a clinician may assume the patient's disease is the limiting factor as opposed to the device's capabilities (or lack thereof). A clinician will assume that if the patient is on the right setting on their portable oxygen system that something other than device operation is the culprit.

Dose and FiO_2 vary with Device and Respiratory Rates

The data in this paper demonstrates the variability of oxygen dose and FiO_2 at different settings and respiratory rates. Each device has a unique performance with some characteristics being similar. It is important to know these differences so the right device can be used for the right patient. More importantly, titrating a patient on their oxygen delivery device with an FDA approved pulse oximeter designed to read through motion and low perfusion assures the clinician and patient of the right setting.

A frequent clinician and DME provider response to a patient not oxygenating sufficiently when on a POC is to cease using the POC, on the assumption that the POC is part of the problem. Not all POCs work the same and it is important that clinicians understand this. Clinicians should appreciate the capabilities and limitations of POCs so they can be a valuable resource to patients when sourcing and selecting a portable oxygen concentrator that adequately meets their clinical needs and personal expectations. Clinicians and DME providers need to be aware of the variability between POCs and the subsequent clinical effectiveness that each POC can deliver. Further, industry experts should consider standardizing POC flow settings to provide DMEs and healthcare professionals with a degree of consistency when educating their patients on device usage.

Conclusions

Product variability exists between tested POCs.

Two methods of gas delivery, minute volume (variable with respiratory rates) and fixed pulse (to the gas producing limits of the devices) are the current technologies used by manufacturers of portable oxygen concentrators.

Product variability impacting capabilities of current POCs may have an impact on therapy. Clinicians and patients should know the operation and capabilities of the POCs being used to determine the right choice for the patient needs.

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